The New Jersey
Pharmaceutical Environmental Committee
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July 15, 2003

VIA REGULAR MAIL

OSWER Docket
EPA Docket Center
Environmental Protection Agency
Mail code: 5305T
1200 Pennsylvania Ave. NW.
Washington DC 20460
Attention Docket ID No. RCRA-2003-0012; FRL-7506-9

Re: Comments on Management of Hazardous Waste in Research and/or Academic Laboratories
New Jersey Pharmaceutical Environment Committee (NJPEC)

Dear Sir or Madam:

The New Jersey Pharmaceutical Environmental Committee (NJPEC) represents pharmaceutical companies in the State of New Jersey, which has thousands of laboratory personnel working in quality and analytical laboratories on our NJ facilities. We applaud the efforts of the USEPA to revise the rules on Hazardous Waste Management in research and academic labs and ask that you extend the modifications to quality and analytical laboratories as well.

Regarding the items discussed at the stakeholder meeting we have the following comments:

1. <u>Hazardous Waste Determination, Labeling, and Training</u>

Laboratory personnel should be trained on a procedure, process, or management systems for handling waste or surplus material. This approach would be consistent with current training practices used by many laboratories to ensure quality and safety. RCRA required training should be limited to support personnel in waste accumulation or storage areas.

We feel that the emphasis should be placed on labeling of chemicals in the laboratory so RCRA trained personnel can make proper waste determinations. It is impractical to put all technical information on the label. The label should help RCRA personnel match the container to a material safety data sheet or waste information profile. Laboratory personnel

only need training on a procedure, process, or management system for handling waste or surplus material.

2. Satellite Accumulation Time

The NJPEC believes there are more problems with the Satellite Accumulation Area (SAA) than just accumulation time. The SAA definition does not work in a laboratory setting and should not be used.

First, an SAA must be "*at or near the point of generation*" and "*under the control of the generator*". With hundreds of researchers in a facility how will generator be defined and interpreted? Many of our members have several inspections a year by both Federal and State regulators and no two interpretations are the same. Some interpretations are based on physical distance, others require a "lock and key" to prove control, others base it on how frequently containers are emptied.

Secondly, RCRA law requires labeling waste in an SAA with the words "*hazardous waste*". It must be dated when full and moved within three (3) days. Applying this requirement to a laboratory would undermine any attempt to use a management system approach as noted in point 1 of this letter.

Lastly, only 55 gallons of a waste (1 kg acutely toxic waste) can be kept in an SAA. This requires making waste determinations and maintaining a detailed inventory in the laboratory. This also undermines any attempt at an alternate system for waste handling in the laboratory.

In conclusion, USEPA must seriously consider replacing the SAA definition with a management system requirement for waste handling.

3. **Treatment Performed in Laboratories**

The laboratory chemists working within our organizations generally have advanced degrees and may have more knowledge of their material than an outside disposal vendor. Therefore treatment of small quantities should be allowed in the laboratory to minimize hazards to outside personnel. Unfortunately, USEPA regulations are confusing and guidance documents complex in defining what can and can't be done. USEPA can encourage treatment by allowing laboratories to replace RCRA defined treatment limitations with a procedure or management based system.

4. Other Issues

Members of the NJPEC employ a large number of laboratory personnel to ensure our drugs are effective, safe, and meet Food and Drug Administration (FDA) requirements. The research laboratory issues, which resulted in this public hearing, are also present in our quality laboratories. Therefore, we strongly request USEPA consider applying future regulation streamlining to quality and analytical laboratories. The NJPEC is willing to discuss this matter in further detail with USEPA if necessary.

Finally, a common thread in this whole process is management systems. Current regulations give too much detail on how to handle waste (e.g. the process). Instead, regulations should define goals and allow regulated entities to develop the appropriate management process. This basic approach would eliminate the complexity and confusion in applying waste regulations to the laboratory.

The NJPEC appreciates USEPA's interest in addressing current difficulties managing laboratory waste. If USEPA desires more information, I can be reached at (973) 385-7111 with questions. Thank you.

Sincerely,

Carolyn Seifried, Chair
NJPEC

cc: NJPEC (via e-mail)